7.0 510(k) Summary of Safety and Effectiveness:

A. Submitter Information:

Submitter's Name:	Davol, Inc.
Address:	Subsidiary of C. R. Bard, Inc. 100 Sockanossett Crossroad Cranston, RI 02920
Telephone:	401-463-7000 Ext. 2386
Fax:	401-463-3845
Contact Person:	Lucinda L. Fox

B. Device Name:

Salute Fixation System

C. Predicate Device Name:

Salute Stapler and Staples
(Onux Medical, Inc.)

D. Device Description:

The **Salute** Fixation System consists of a reusable handle, shaft and shaft tip, as well as a sterile, disposable implant cartridge with wire support tube and cover. The disposable implant cartridge comes preloaded with 316L stainless steel wire. The device is used to deliver permanently implanted Q-shaped rings (Q-ring). Depending on user preference, the handle may be used with an 18cm shaft or a 38cm shaft (fits into a 5mm trocar). Implant cartridges are offered with sufficient 316L stainless steel wire to form 10, 20, 30, or 50 Q-rings and are designed to work with either a 38cm shaft or an 18cm shaft. The handle and shaft are engraved with serial numbers, which must match in order for the device to function properly. The Instructions for Use (IFU) contain information to insure the implant cartridge is used with an appropriate shaft and to confirm the serial numbers of the shaft/handle match.

K050610
page 2/2

E. Intended Use:

The **Salute** Fixation System is indicated for use in a variety of laparoscopic/endoscopic or open surgical procedures for fixation of prosthetic material and approximation of tissue.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The Proposed and Predicate devices are designed to place stainless steel sutures in tissue/prosthetics. Both Proposed and Predicate devices consist of a reusable handle and shaft, which are used to deliver permanently implanted, stainless steel Q-shaped rings from a disposable implant cartridge. The key differences between the Proposed and Predicate devices are: Initial wire penetration depth of the Q-ring as it is deployed, which required a change to the wire diameter from 0.017" to 0.018"; the addition of a 18cm shaft for use in open surgical procedures and addition of associated implant cartridges; and, the addition of implant cartridges with 30 and 50 Q-rings, which involved driving the wire as it was pulled off the spool.

Although the Proposed's shaft tip was modified to deepen the wire's initial penetration into tissue/prosthetic, the overall diameter/configuration of the Q-ring was not changed. Increasing the depth of the wire's initial penetration merely enhances the Q-ring's ability to approximate tissue/ attach prosthetics. However, since the Proposed and Predicate Q-rings are comparable in terms of diameter and shape, their tissue/prosthetic fixation capabilities are the same. Although the Proposed contains new materials as a result of the "driven" wire and PTFE material change, these may be assessed using the same biocompatibility testing completed for the Predicate.

G. Performance Data

Biocompatibility will be completed and passed before the new PTFE material is released. Bench testing on the Proposed demonstrated the Q-ring shape and dimensions were substantially equivalent to the Predicate. Therefore, the Proposed device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2005

Ms. Lucinda L. Fox
Manager, International Regulatory and Clinical Affairs
Davol Incorporated
100 Sockanossett Crossroad
Cranston, Rhode Island 02920

Re: K050610
Trade/Device Name: Salute® Fixation System
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: March 8, 2005
Received: March 10, 2005

Dear Ms. Fox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: ~~Unknown~~ K050610

Device Name: Salute® Fixation System

Indications for Use:

The Salute® Fixation System is indicated for use in a variety of laparoscopic/ endoscopic or open surgical procedures for fixation of prosthetic material and approximation of tissue.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K050610